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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61N 1/40 — A1

(11) International Publication Number: **WO 00/09208**

(43) International Publication Date: 24 February 2000 (24.02.00)

(21) International Application Number: PCT/BE99/00106

(22) International Filing Date: 13 August 1999 (13.08.99)

(30) Priority Data:
1009868 14 August 1998 (14.08.98) NL

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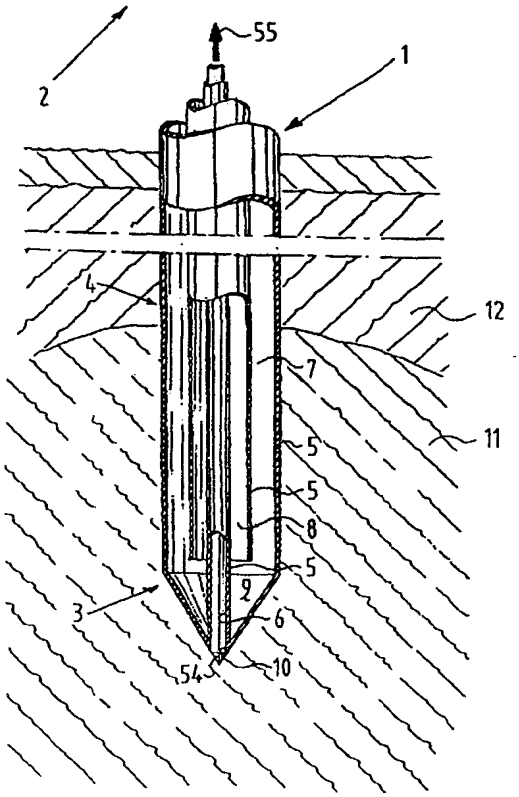
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: COOLED–WET ELECTRODE

(57) Abstract

The invention relates to device for delivering radio–frequency (RF) energy, for example during tissue ablation procedures, comprising an electrode (1) having a distal end (3) associated with tissue puncturing means and a proximal end (2) connectable to a radio frequency energy source, wetting means for wetting the proximaty of the distal end (3) of the electrode with a non–toxic (RF) conductive solution and cooling means for cooling at least the distal end of the electrode. The invention further relates (to the use of the device according to the invention and) to a process for cooling and wetting a radio frequency energy delivering device and to a guidance element therefor.



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COOLED-WET ELECTRODE

The invention relates to novel devices for delivering radio frequency energy (RF), for example during tissue ablation procedures.

The invention relates in particular to a novel concept of an electrode for the optimization of radio frequency ablation. This concept will hereunder be nominated as the cooled-wet electrode.

Although surgical resection is still considered as a primary option for the treatment of malignant tumors, minimally invasive alternatives including intraoperative cryosurgery, local injection of ethanol, microwaves, interstitial laser therapy focused ultrasound and radio frequency (RF) tissue ablation have been developed in order to ablate the tumor less invasively for the safety of the patient and reduction of the costs and/or to broaden our capability in treatment of the patient.

Among these approaches, RF ablation has shown the greatest impact on recent experimental and clinical research because of its low invasiveness, simplicity and favorable cost-effectiveness.

In RF ablation the radio-frequency waves are emitted from a generator through an uninsulated part of the electrode which is inserted into a target tissue. The tissue destruction in a form of coagulation necrosis is caused primarily by resistive heating in the surrounding tissue and secondarily by the peripheral passive heat conduction.

Resistive heating is proportional to the square of the distance between the central electrode and adjacent tissue. Therefore, significant resistive heating only occurs within a rim of tissue in direct contact with the electrode. Beyond this rim, the tissue is further heated as a result of passive conduction of increased temperature. However, the RF emission is readily terminated as a result of impedance rise at the electrode-tissue interface, which is secondary to tissue desiccati-

on and carbonization. Due to such non-optimal RF energy delivery and dissipation, the lesion size induced by known prototypes electrodes is smaller than 2 cm, which is obviously insufficient for tumor ablation. Similar to the principle in surgical resection, the ideal range of RF tissue destruction should involve the entire tumor and a layer of adjacent normal tissue as a safety margin to avoid incomplete ablation.

Many known technical innovations have been made to increase the lesion size in RF ablation. These include the introductions of:

1) bipolar electrodes;

2) a cooled electrode and cooled-clustered electrodes;

3) a "wet" electrode with hypertonic saline infusion; and

4) an expandable electrode.

According to the principle of minimal invasiveness, a monopolar is preferred to multipolar electrode.

As shown in table 1, although markedly increased, the lesion sizes induced by these modified devices are still limited, normally less than 4 cm in diameter. If a tumor larger than 2 cm, there is little chance to achieve complete ablation by a single session. Therefore there is still a demand to further optimize these devices and techniques.

Table 1 shows the lesion sizes induced by different known designs of electrode in RF Ablation.

Table 1

Electrode Type	Lesion size (cm)	No. Reference
Prototype Electrode	0,8 - 1,5	1
Bipolar Electrode	5 (the width between poles)	2
Cooled Electrode	1,4 - 3,6	3
Wet Electrode	4,5 ±0,75	4
Expandable electrode	4,5	5,6
Cooled-clustered	4.7 ±0.1	7

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The main object of the invention is to provide a new device and methods yielding good RF ablation results and providing larger lesion size. In particular whereby the lesion size is larger than 5 and preferably more than 6 cm.

According to the invention this is realized by a combination of separately known features, which in combination surprisingly results in a more effective RF ablation. This is realized by an increased conductivity of the target tissue as well as at the electrode tissue interface in relation to a decreased tip temperature.

The invention therefore provides a device for delivering radio-frequency energy combining the characteristics of a "wet" electrode and of a cooled electrode.

In achieving the above mentioned objects the invention provides a device according to claim 1. The

preferred embodiments are defined in the subclaims 2 to 7.

A main object is a minimal invasiveness of the radio-frequency ablation technique. A minimal invasiveness is obtained by a precise puncturing and guidance towards the tissue to be treated. It is therefore a further object of the invention to improve the efficiency of the puncturing and guidance of the radio-frequency electrode and more broadly of all instruments used in RF ablation. The puncturing is presently performed by the sharpened distal end of the electrode. As this distal end is often open introduction sometimes causes obstruction and once introduced blocks off these openings at the distal tip. It will be understood that the use of guidance means is not necessary for the use of the cooled wet electrode. The puncturing can be performed by the sharpened distal end of the cooled wet electrode as sole puncturing mean.

As a solution to this disadvantage the invention provides further a separate guidance element for the guidance of an instrument, in particular a radio-frequency electrode. The guidance element according to the invention is substantially formed by a open hollow shaft having a cilindrical central bore which is adapted in dimensions for the temporarily housing and axial displacement of an instrument during radio-frequency ablation procedures. Said instrument can be for example a puncturing needle for a smooth introduction towards the tissue to be treated, a radio-frequency electrode for the radio-frequency ablation step and further a biopsy needle or biopsy clamp for providing proof of the efficiency of the radio-frequency ablation procedure by the collection of a tissue sample.

The invention further relates to the use of a device according to the invention as claimed in claim 10 and to a method as defined in claims 11-12.

It will be understood that several cooled wet electrodes, for example two, three, four or more can be

used as a clustered cooled wet electrode device when the tumor to be treated is of an excessive dimension.

The invention shall be elucidated hereunder with reference to the drawing wherein schematically is shown in:

figures 1 to 7 partially broken away cross-sectional and perspective views of five preferred embodiments of the cooled-wet electrode according to the invention;

figure 8 a schematic illustration of radio-frequency ablation system using a cooled-wet electrode according to the invention;

figure 9 a partial broken away perspective view of a guidance element (figure a), a puncturing needle (figure b) and a biopsy needle (figure c).

In the figures the thin printed arrows define the flow pattern of a cooling medium and a wetting medium and the bold printed arrows the direction of the movement of parts of the electrode. The cooling and wetting medium are preferable solutions and in a preferred embodiment the wetting solution is a saline solution and more preferably a hypertonic (for example 0.9% saturated) saline solution. The cooling solution is preferably water or cooled media such as 0°C saline.

A rigid hollow needle electrode 1 comprises a proximal end 2, a distal end 3 and there between a longitudinal part 4. The electrode 1 comprises a number of cilindrical wall elements 5 forming three concentric channels, i.e. an inner concentric channel 6 and two outer concentric channels 7, 8, which outer concentric channels 7, 8 are connected at the distal end 3 of the electrode 1 forming a closed loop 9. The outer concentric channels 7, 8 define a flow path for a cooling solution such that at least the distal end 3 of the electrode 1 can be sufficiently cooled.

The inner concentric channel 6 is open 10 at the distal end 3. The inner concentric channel 6 defines the flow path for the wetting solution and a housing for

puncturing means which is formed by an axial (arrow 55) retractable and protruding pith organ 54. The pith organ 54 closes the open end 10 when being inserted into the target tumor 11 in order to avoid obstruction in the channel 10. An accesory biopsy needle of the same size can be replaced before ablation for sampling tumor tissue for histopathologic examination. After insertion of the electrode 1 the pith organ 54 is retracted upwards making free the flowing path of the wetting solution in the channel 6 (figure 2). When the electrode 1 is introduced towards a tumor 11 on a target organ 12 radio-frequency energy will be delivered via a non-insulated part of the electrode 1, being at least the distal end 3 of the electrode 1 while simultaneously the distal end 3 is cooled by a cooling solution and the proximity of the distal end 3 is being wetted 13 by a wetting solution. The distal end 3 of the electrode 1 is preferably sharpened such that is has a further puncturing function. The separate flow control of the cooling and wetting for example in concentration, temperature, etc. results in a superior lesion size.

The electrode 1 has in general a substantially rigid structure in order to be able to be aimed precisely in the tumor.

The axial slidable pith organ 54 is used in order not to obstruct the channel for the wetting solution 6. Once the electrode 1 is positioned in the centre of the tumor 11 the pith organ 54 is upwardly retracted and removed. A RF-energy delivery can start when the pith 54 is retracted and the wetting solution 13 is delivered simultaneously with the RF-energy.

The embodiment disclosed in figure 3 comprises two concentric channels 27 and 28 forming a closed loop at the closed end 29 of the distal end 30. This closed loop channel (27,28) defines the flow channel for the cooling solution as arrows 31 (down) and 32 (up) indicate (comparable to figure 2). At the distal end 30 an open lateral channel 33 is provided as flow path for the

wetting solution, which is preferably a hypertonic saline solution. At the distal end 30 the channel 33 is provided with multiple openings 35 for the outflow of the wetting solution 13 in order to create sufficient spreading of the wetting solution 13 at the proximity of the distal end 30. Arrows 36 (down) and 35 (out) define the flow path for the wetting solution.

The diameter of these needle electrodes should preferably be as small as possible and is preferably smaller than 3 mm.

The embodiment of the electrode 37 depicted in figure 4 comprises three concentric channels: an outer channel 38 provided with multiple holes 41 at the distal end 42 of the electrode 37 and two concentric channels 27 and 28 forming a closed loop 29 at the distal end 42 of the electrode 37 and defines the flow path for the cooling solution.

The electrode of figure 5 discloses another preferred embodiment wherein a separate lateral channel 44 for the wetting solution 13 is provided having at the distal end 45 of the electrode a helical formed part 46 around the distal end 45 of the electrode and is provided with multiple openings 48 in order to create a flow path for the wetting solution through and out the electrode.

In the embodiment of figure 6 the cooling and wetting solution is one and the same thus. This has the advantages of a more compact and simpler structure of the electrode 49. However, in the other embodiments the separate flow rate can be adjusted for their purposes i.e. the cooling solution normally has a higher flow rate than the wetting solution.

The embodiment of figure 7 discloses a further preferred embodiment comprising an axial (arrow 56) slidable temperature measurement organ 44 comprising multiple thermosensors 50 on a determined distance of each other. Normally radiofrequency radiation and energy will spread radially in relation with the distal end of the electrode. The retractable thermosensor will provide in

an objective manner a measurement of the efficiency of the radiofrequency ablation method.

The use of these concentric channels does not only provide the advantage of a sufficient and controlled flow rate but also the synergetic effect that the wetting solution is simultaneously cooled off.

It is obvious for a skilled man that any combination of the form or the position of the channels, the described central pith and the retractable thermosensor can be varied, for example the central thermosensor can be positioned laterally, also the pith can be positioned in a different manner without departing from the scope of the invention.

Figure 8 depicts a schematic illustration of the radio-frequency ablation of a target tissue 11, for example the liver with a cooled-wet electrode of the invention. The cooling means 57 comprise in general a reservoir 58 for a cooling solution connected to an opening 59 at the proximal end 60 of an electrode 61 and further comprising circulation means 62 in order to circulate the cooling solution.

The wetting means generally contain an infusion pump 63 connected to a hypertonic solution 64 and connected to the opening 59 at the proximal end 60 of the electrode 61. The proximal end 60 of the electrode 61 is connected to a radio-frequency energy source 65 and in order to close the electric circuit a ground path 66 is provided under the organ 11. The lesion size is substantially enlarged by using a cooled/wet electrode of the invention up to 6-10 cm.

If appropiate temperature control means are further provided at the distal end of the electrode to monitor and to control the temperature. All the depicted configurations of channels and elements in or on the electrode are, as is obvious adjustable and combinable or interchangable.

Guidance element 100 is substantially formed by an open elongated shaft 101 provided with a central

cilindrical bore 102 and a open blunt distal end 103. The diameter of the cilindrical bore 102 is thus adjusted that instruments to be guided by the guidance element 100 can be introduced and be displaced in the axial direction of the bore with a minimal radial tolerance but still providing smooth axial guidance. The puncturing can preferably be performed by a puncturing needle 104 which is introduced in the guidance element 100 and provided with a sharpened distal end 106 being used as a puncturing mean for introducing of the combination guidance element 100 and needle 104 towards to the tissue to be treated. A smooth introduction can be obtained due to the sharpness and to the form and dimensions of the needle 104. Once introduced the needle 104 is retracted out of the cilindrical bore 102 of the guidance element 100 while maintaining the introduced position of the guidance element 100. A radio-frequency electrode can then be entered through the cilindrical bore 102 of the guidance element 100 until protruding at the distal end of the guidance element 100. When the radio-frequency ablation procedure is terminated, the electrode is retracted out of the guidance element 100, while this element is maintained in the previous obtained position.

For providing proof of the efficiency of the radio-frequency ablation a biopsy needle 109 can be introduced through the same cilindrical bore of the guidance element 100 towards the treated tissue. The distal end of the biopsy needle 109 is provided with a clamp 108 for collecting treated tissue samples for further investigation.

The advantages and the specific characteristics of the cooled-wet electrode are founded on the following experiments.

Materials and methods of the experiments:
The subjects of RF ablation are:

1. Commercial beef liver: 4 pieces of beef livers of about 10 kilograms each were purchased from a

local butcher. The temperature of the liver was warmed up from 4°C to room temperature before RF ablation.

2. Swine liver: fifteen livers were excised from the pigs and immediately brought to the site of RF ablation.

3. Twelve domestic pigs of 40-60 kg body weight.

The used equipment comprised a demo RF generator (RFG-3E, Radionics, USA); a cooling pump: Watson-Marlow 31.3 (Watson-Marlow Limt. England); a wetting saline infusion pump (Ismatic, Switzerland); cool-wet electrodes according to the invention and a MRI scanner: 1,5 Tesla Mangetom Vision (Siemens, Erlangen, Germany).

Experimental groups ex vivo tests:

1. Group A: Conventional RF mode, 22 sites of ablation (without cooling perfusion and saline infusion)

2. Group B: Cooled only mode: 27 sites of ablation (RF at 50 W for 10 min with cooling perfusion at 40 ml/min)

3. Group C: Wet only mode: 20 sites of ablation (RF at 50 W for 10 min with 5% saline infusion at 1 ml/min)

4. Group D: Continuing cooled-wet mode, 20 sites of ablation (RF at 50 W for 10 min with 5% saline infusion at 1 ml/min and cooling perfusion at 40 ml/min)

5. Group E: Cooled-wet mode with disconintuing saline infusion, 20 sites of ablation (RF at 50 W for 10 min with cooling perfusion at 40 ml/min and 5% saline infusion at 1 ml/min for only first 5 min)

6. Group F: Cooled-wet mode with discontinuing cooling perfusion, 13 sites of ablation (RF at 50 W for 10 min with 5 % saline infusion at 1 ml/min and cooling perfusion at 40 ml/min and for only first 5 min)

7. Group G: RF of cooled-wet mode by manual control at 70-90 W during 10-30 min:10 sites.

In vivo liver ablation in the swine:

Under general anesthesia and intubated ventilation, 12 swines were laparotamized with left and right

liver lobes exposed for RF ablation. Under laparotomy, 72 RFA lesions were created in 12 pigs using a novel "cooled-wet" elecrode that combines internal cooling perfusion and hypertonic saline interstitial infusion. Both power control mode (Group A. cooled only, B. wet-only and C. cooled-wet) at 90 W and manual control mode (Group D. cooled-only, E. wet-only and F. cooled-wet) were compared for impedance, current and lesion size. MRI was performed for measurement of lesion size. T1 and T2 weighted MR1 were performed immediately after RF ablation.

The results in ex vivo tests with excised pork and beef livers are summarized in table 2. RF ablation at 50 W for 10 min created the largest lesion size with cooled-wet mode (group D) right than with any other modes left. Continuity of RF energy delivery was ensured only in group D, so that the lesion size reached close to 10 cm if ablation duration was prolonged to 30 min and the power was set to 70-90 W. Due to a sudden increase of impedance in other groups sooner or later after ablation started, the delivery of RF energy almost ceased and the lesion size did not further increase.

Table 2

Group	No. Sites	Saline Infusion (ml/min)	Tip Cooling Perfusion (ml/min)	Tip Temp. (°C)	Power Output (W)	Impedance (Ò)	Current (A)	Lesion Size (cm)
A	22	0	0	93,6±3.9	13.7±1,5	>900	0,13±0,1	0,86±0,3
B	24	0	40	31,5±4,8	16,1±3,3	81,2±16,5	0,85±0,1	2,43±0,5
C	18	1	0	99,6±0,9	45,2±10,8	99,8±113,4	0,94±0,4	3,80±0,5
D	20	1	40	35,9±6,8	49,5±2,4	55,8±50,7	1,14±0,2	4,90±0,6
E	20	1x5min	40	42,9±4,4	17,8±2,7	725,6±229,3	0,15±0,0	3,89±0,6
F	13	1	40x5min	99,5±0,9	38±12,2	412,5±138,3	0,46±0,4	4,27±0,5

Notes:

1. Group A: Conventional RF mode, (without cooling perfusion and saline infusion)

2. Group B: Cooled only mode (RF at 50 W for 10 min with cooling perfusion at 40 ml/min)

3. Group C: Wet only mode (RF at 50 W for 10 min with 5% saline infusion at 1 ml/min)

4. Group D: Continuing cooled-wet mode according to the invention (RF at 50 W for 10 min with 5% saline infusion at 1 ml/min and cooling perfusion at 40 ml/min)

5. Group E: Cooled-wet mode according to the invention with discontinuing saline infusion (RF at 50 W for 10 min with cooling perfusion at 40 ml/min and 5 % saline infusion at 1 ml/min for only first 5 min)

6. Group F: Cooled-wet mode according to the invention with discontinuing cooling perfusion at 40 ml/min for only first 5 min).

The swine tolerated in the in vivo tests the RF ablation well and life signs were kept normal during and after ablation. The lesion size appeared smaller than that in ex vivo tests probably due to the cooling effect from hepatic inflow. In vivo results: together with lower impedance and higher power output, the lesion sizes in group C (4.8±0.6 cm) and F (6.5±0.8 cm) were significantly larger ($P<0.01$) than that in group A (2.4±0.5 cm), B (3.1±1.0 cm), D (3.3±0.6 cm) and E (3.5±0.9 cm).

In RF ablation with a cooled electrode, the inner cavity channel of the electrode is preferably irrigated with cold or tap water. By the cooling effect, the distal end tip of the electrode is maintained at low temperature and free of charring thereby facilitating the conductivity of electrode-tissue interface and preventing an impedance rise. However, to a certain extent, the lesion size can no longer be further increased, because

1) the dimension of the electrode and hence the adjacent areas ablated with resistive and conductive heating are limited;

2) the conductivity of the tissue itself is relatively low if no external conductive agent is added;

3) steaming and tissue desiccation always occur next to the electrode-tissue interface which causes a rise of impedance.

The technique of a wet electrode and of a cooled electrode were separately known and eventuate in several drawbacks.

In RF ablation with a wet electrode, a hyper-conductive saline as an example of a wetting solution is prior and continuously infused via a the electrode into the target tissue while RF energy is delivered. The conductivity of 0,9% normal saline is 3-5 times higher than that of the blood and 12-15 times higher than that of tissues. With more than 5 times of increased concentration, further improvement of conductivity is expected. Infused saline functions as a "liquid electrode" within the tissue to be ablated and spreads applied RF energy away from the metal electrode to the surrounding tissue. Therefore, both the central resistive heating rim and peripheral passive heating area are increased, hence a larger lesion can be obtained. When saline is infused, some convective cooling also occurs at the tip. Besides, steaming is retarded by the increased boiling temperature of tissue fluid in which hypertonic saline is added. The effect of RF ablation with saline infusion appears already superior to that with cooling perfusion. However, this was still not optimal. The tip temperature still frequently raises above the boiling temperature at the electrode-tissue interface. Furthermore, infusion of a large amount of saline into the tumor may increase the static interstitial pressure which in turn may force individual tumor cells to migrate into adjacent or remote areas.

As demonstrated in our experiments, the current invention of cooled-wet electrode combines the advantages and meanwhile overcomes the disadvantages of each separate technique, yielding an optimal result of RF ablation with lesion sizes larger than 6cm. This is realized by an increased conductivity of the target tissue as well as at electrode-tissue interface and a decreased tip temperature. The amount of infused saline can be reduced in comparison to that in "wet" alone mode. Unlike other more

invasive approaches such as RF with bipolar, clustered and expanded electrodes and multiple applications of a single electrode, the present cooled-wet embodiment only use a single needle, through a single puncture but cause a large lesion ideal for tumor ablation or eradication. The proposed cooled-wet electrode and the described procedure allows to obtain by a single needle and in one session, a lesion of sufficient size. This is in contrast with the currently existing devices which necessitate either multiple deliveries of expanded electrodes or multiple applications of a single electrode to obtain similar results. Obviously, the application of a single electrode in one session is easier to perform and to control.

CLAIMS

1. Device for delivering radiofrequency (RF) energy, for example during tissue ablation procedures, comprising an electrode having an uninsolated distal end associated with tissue puncturing means and a proximal end connectable to a radio frequency energy source, wetting means for wetting the distal end of the electrode and the proximity thereof with a non-toxic (RF) conductive solution and cooling means for cooling at least the distal end of the electrode.

2. Device according to claim 1, wherein the electrode comprises a first channel for the wetting solution and at least a second channel for the cooling solution.

3. Device according to claim 2, wherein said first wetting channel is open at the distal end and said second channel is closed at the distal end of the electrode.

4. Device according to claim 3, wherein the channels are concentric.

5. Device according to claim 2 or 3, wherein the channel defining the flow path for the wetting solution is helical formed at the distal end of the electrode around an inner channel for the cooling solution and said helical wetting channel comprises several openings at the distal end.

6. Device according to any of the previous claims 1-5 wherein the tissue puncturing means are formed by an inner axial slidable pith organ.

7. Device according to any of the previous claims 1-6 wherein the distal end of the electrode is provided with retractable temperature control means preferably comprising at least two temperature sensors.

8. Guidance element for the guidance of the displacement of an instrument in radio-frequency ablation procedures which guidance element is substantially formed

by an open hollow shaft having a central cilindrical bore.

9. Guidance element according to claim 8, wherein said instrument is chosen from a puncturing needle, a radio-frequency ablation electrode or a biopsy needle.

10. Use of the device as defined in any of the previous claims 1-7 for RF tissue ablation procedures.

11. Process for cooling and wetting a radio frequency energy delivering device as defined in any of the previous claims 1-7 comprising the steps of providing a wetting solution to the proximity at a distal open end of the frequency energy delivering device and providing a cooling of the distal end of said device by transport of a cooling solution in the inner body of said device.

12. Process according to claim 11, wherein the temperature at the proximity of the distal end is monitored by providing multiple temperature measurement means at different distances from the distal end of the electrode.

13. Device according to any of the previous claims 1-7 wherein the electrode is formed by a cluster of several, for example 2, 3, 4 or more seperate electrodes in a parallell alignment.

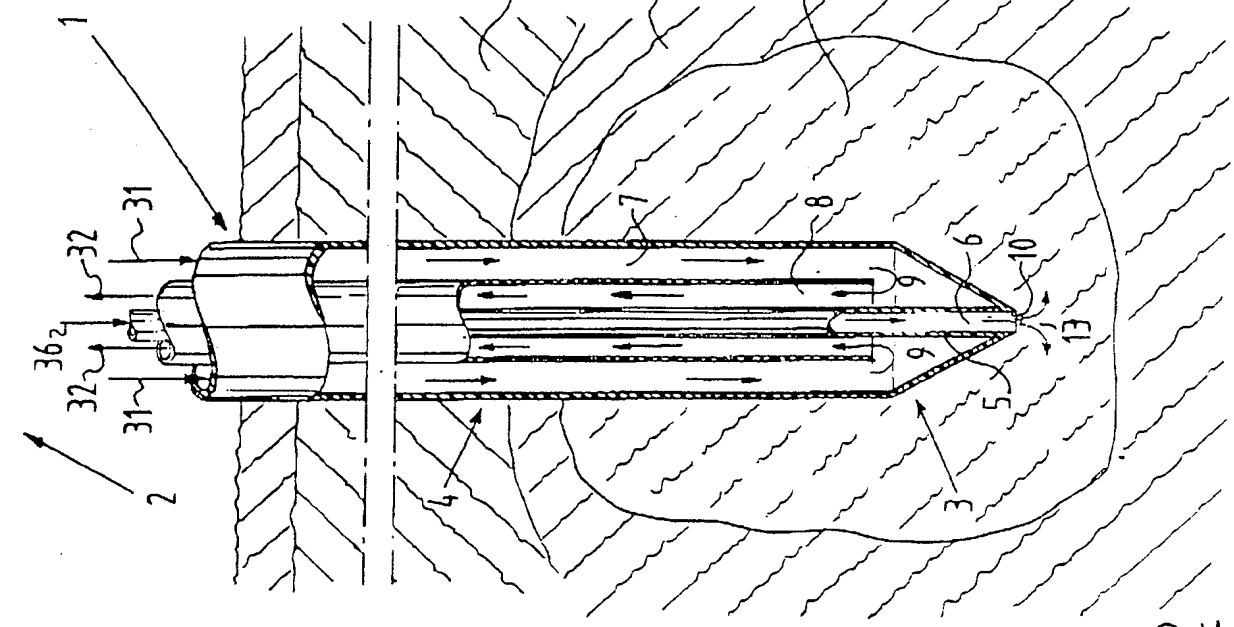

FIG. 2

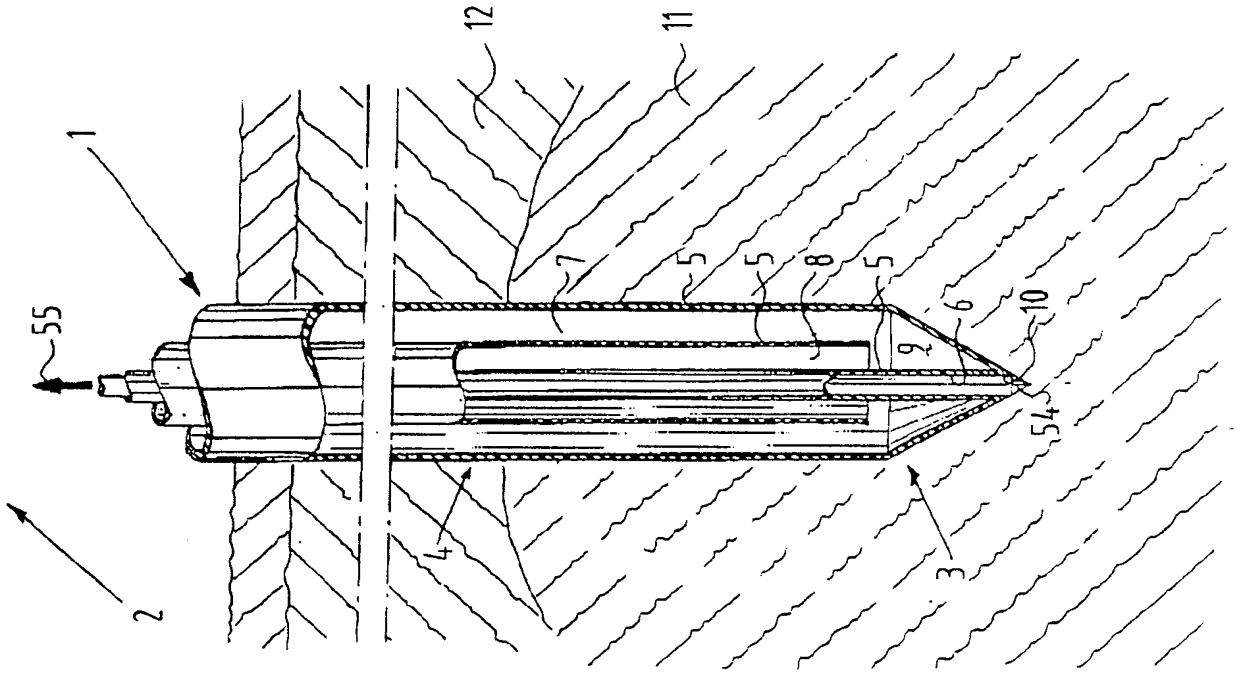

FIG. 1

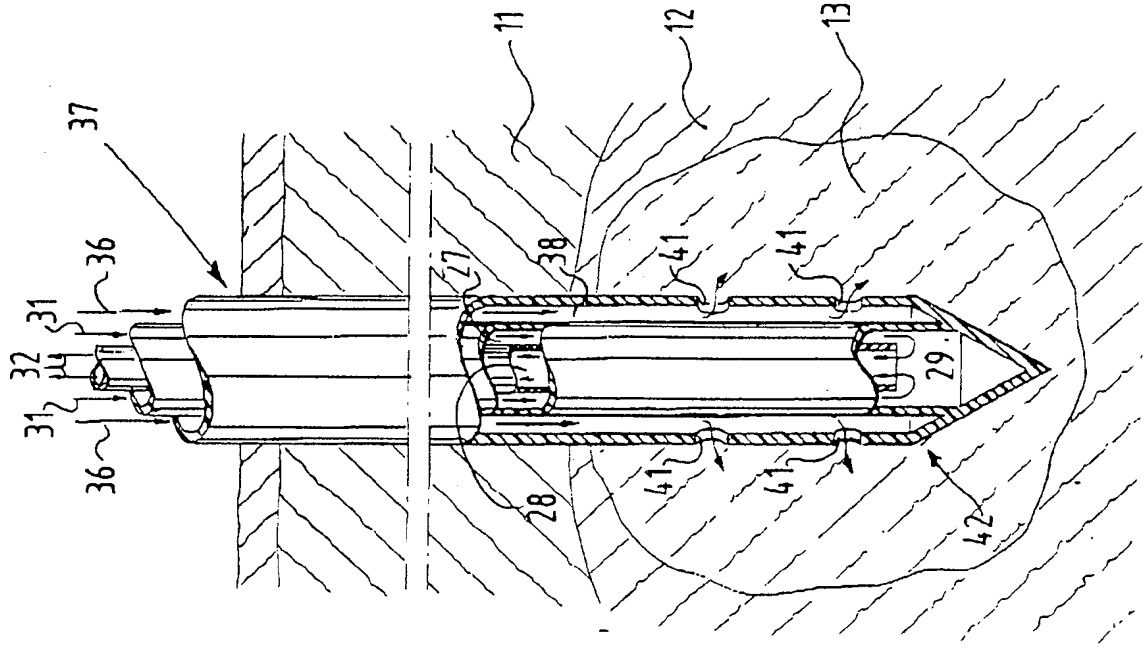
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FIG. 4

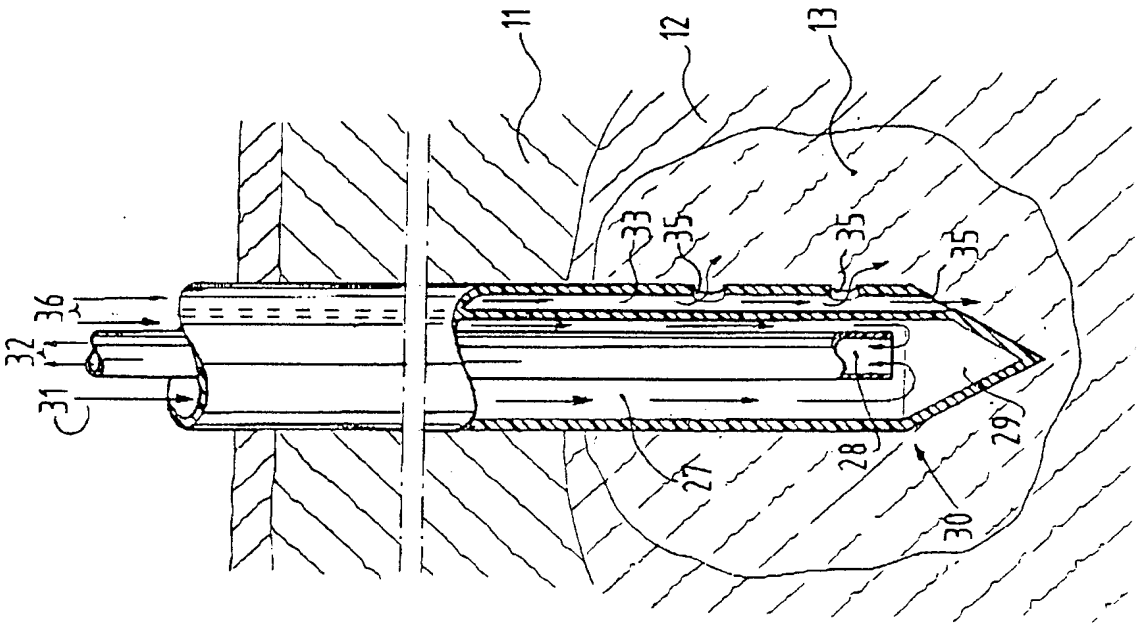
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FIG. 3

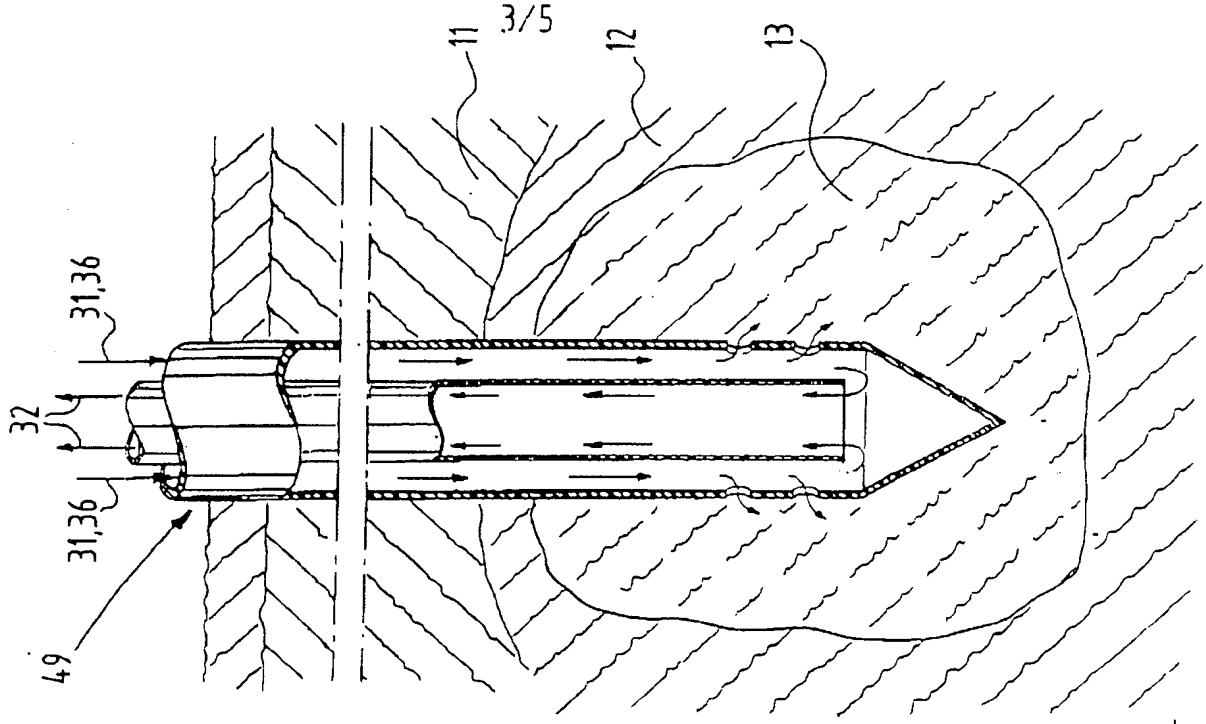

FIG. 6

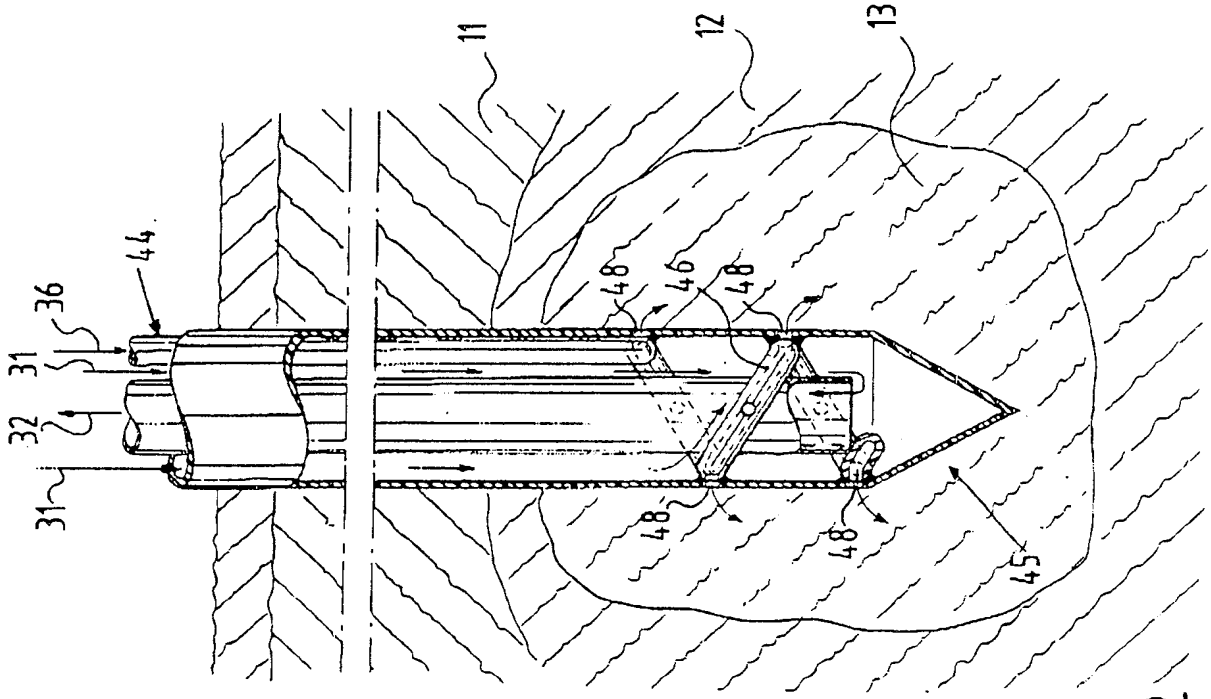

FIG. 5

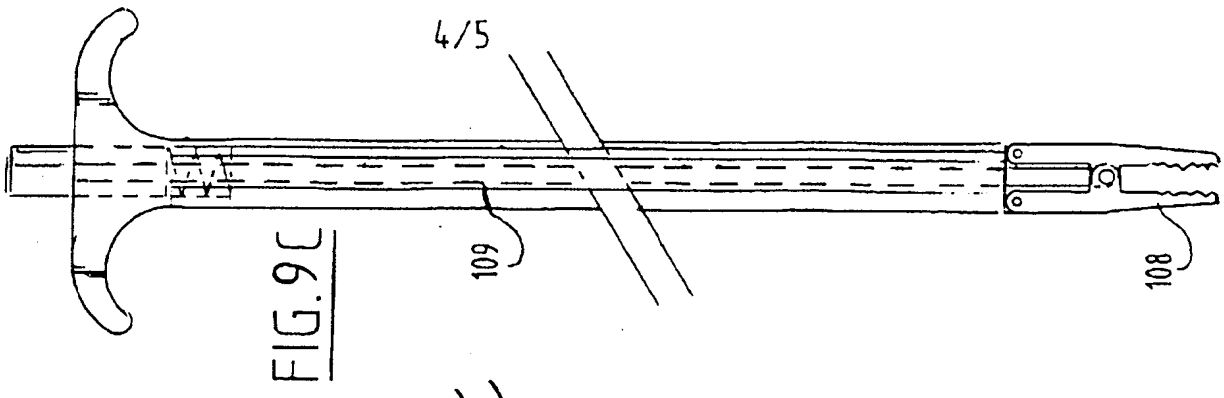

FIG.9C

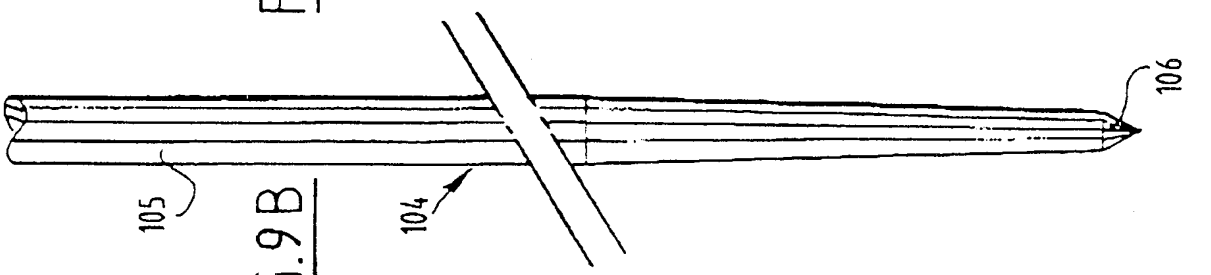

FIG.9B

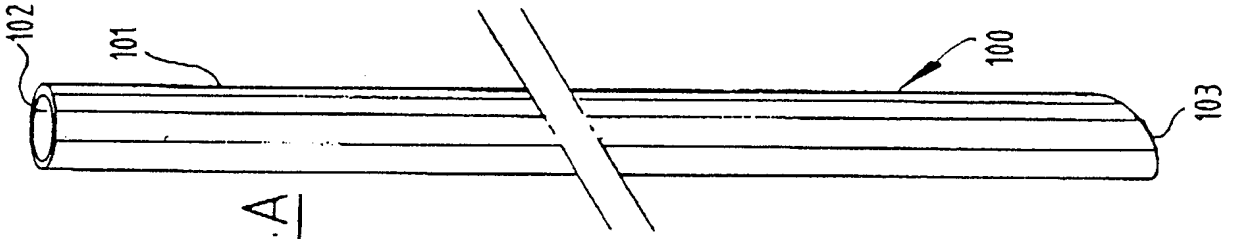

FIG.9.A

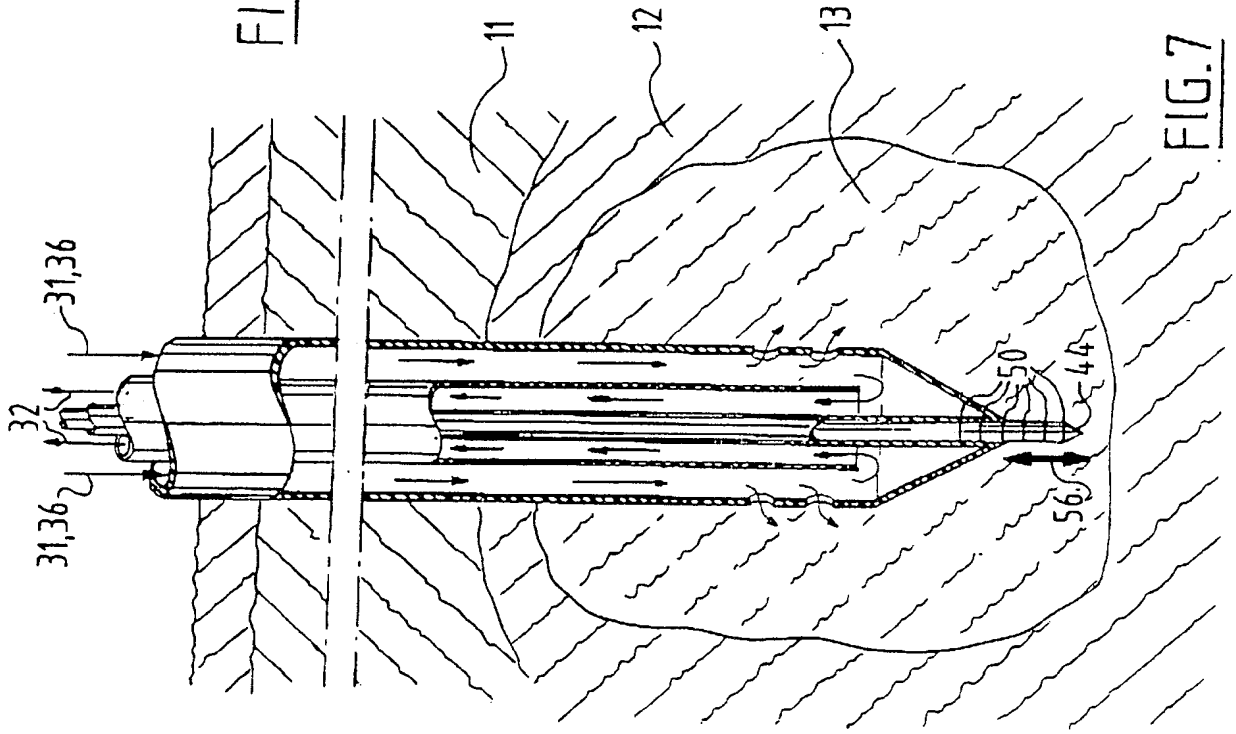

FIG.7

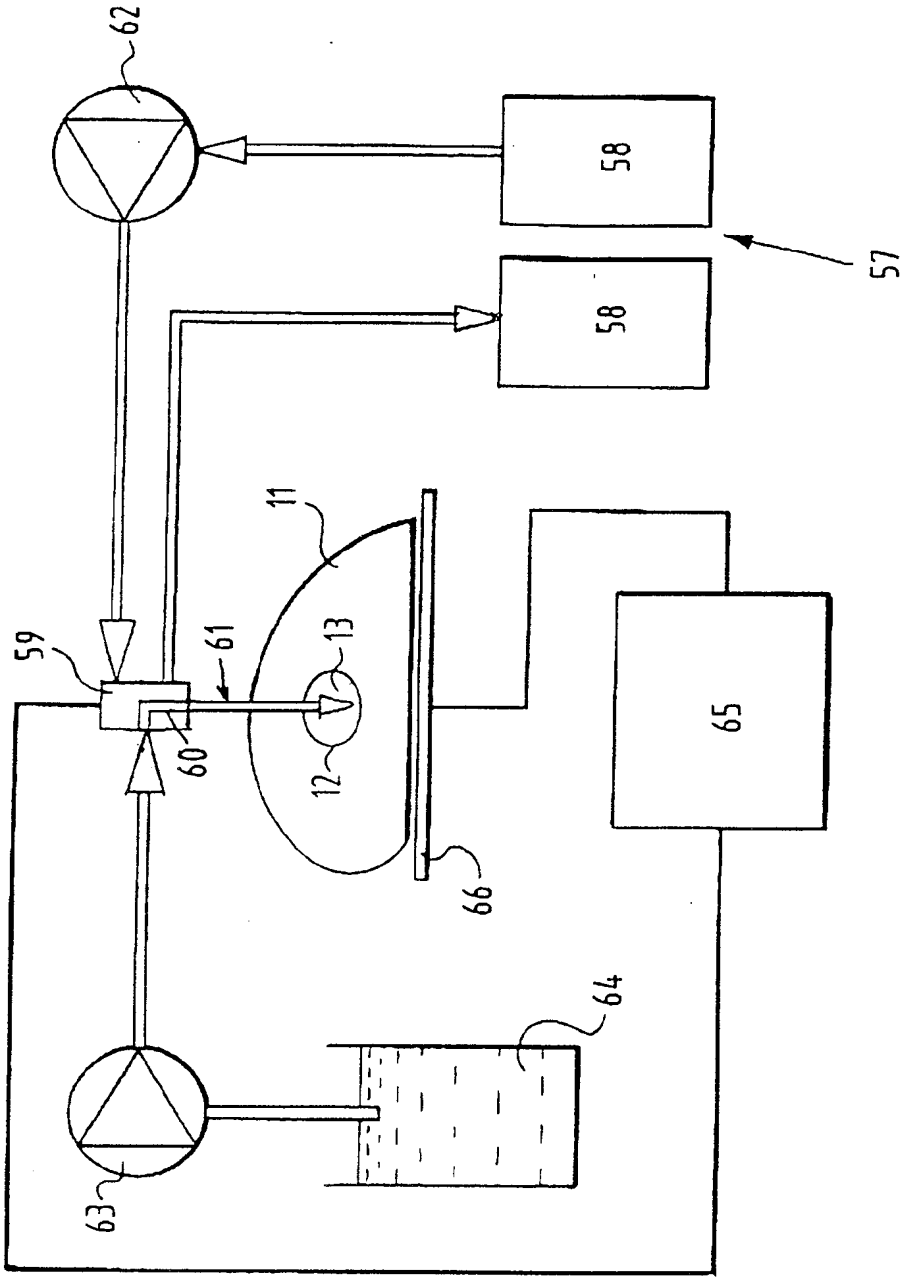

FIG. 8

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/BE 99/00106

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	TORBEN LORENTZEN: "A Cooled Needle Electrode for Radiofrequency Tissue Ablation : Thermodynamics Aspects of Improved Performance Compared with Coventional Needle Design" ACADEMIC RADIOLOGY, vol. 3, no. 7, 7 March 1996 (1996-03-07), pages 556-563, XP000852585 Herlev, Denmark cited in the application the whole document	1-4,6,11

X	WO 98 03220 A (ARTHROCARE CORP) 29 January 1998 (1998-01-29)	8,9
A	page 27, line 32 -page 31, line 3 page 37, line 13 -page 40, line 10; figures 1-4,21-23	1,11-13

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 December 1999	22/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rakotondrajaona, C

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Form PCT ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/BE 99/00106

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	S. ROSSI, E. BUSCARINI ET AL.: "Percutaneous Treatment of Small Hepatic Tumors by an Expandable RF Needle Electrode" AMERICAN JOURNAL OF ROENTGENOLOGY, vol. 170, no. 4, April 1998 (1998-04), pages 1015-1022, XP000852550 cited in the application the whole document	1,2,11, 13
A	EMMA J. PATTERSON CHARLES H. SOUDAMORE ET AL.: "Radiofrequency ablation of Porcine Liver In Vivo : Effects of Blood Flow and Treatment Time on Lesion Size" ANNALS OF SURGERY, vol. 227, no. 4, April 1998 (1998-04), pages 559-565, XP000852579 Hagerstown, Maryland cited in the application the whole document	1,7,11, 13
X	US 5 472 441 A (LAX RONALD G ET AL) 5 December 1995 (1995-12-05)	8,9
A	column 6, line 66 -column 11, line 3; figures 1-5,7,10-13	1,2
A	EP 0 115 420 A (KUREHA CHEMICAL IND CO LTD) 8 August 1984 (1984-08-08) page 7, line 19 -page 16, line 1; figures 3,11-16	1,2,7, 11,12
X	WO 96 32051 A (ARTHROCARE CORP) 17 October 1996 (1996-10-17)	8,9
A	page 16, line 6 -page 18, line 20 page 20, line 15 -page 21, line 37; figures	1,6

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/BE 99/00106

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10.
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inte onal Application No
PCT/BE 99/00106

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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